

## REMARKS

### STATUS OF THE CLAIMS.

Claims 1-35 and 37-39, 41-43, 45-49, 51, and 53-55 are currently pending in the application with entry of the present amendment. Of such claims, 1-34, 38, 45-48, and 53-55 are withdrawn from current consideration, while claim 36 is previously cancelled and claims 40, 44, 50, and 52 are cancelled herein. Claims 35, 37, 39, 43, 49, and 51 are amended herein to more clearly describe embodiments of the invention. These changes introduce no new matter and support is present in the application and claims as originally filed. The changes are made without prejudice and are not to be construed as abandonment of any previously claimed subject matter or agreement with any objection or rejection of record. Accordingly, entry of the Amendment is respectfully requested.

### REJECTIONS TO THE CLAIMS

#### 35 U.S.C. §112 First Paragraph.

Claims 37, 39, 42, 43-44, 49, and 51 were rejected in the Office Action under 35 U.S.C. §112, first paragraph as allegedly lacking enablement for sulfonated compounds other than LSA (or its various other descriptives) in combination with the spermicide, Nonoxynol 9<sup>TM</sup>. The Office Action alleges that the specification does not provide written description enablement for "any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and any compounds having spermicide function (i.e., in claims 39 and 43)." Applicants amend in part and traverse in part.

In regard to the Office Action's contention that the specification does not provide written description enablement for "any sulfonated compounds," Applicants herein amend claims 39, 43, 49, and 51. While Applicants believe that the current claims are enabled by the written description of the specification, such claims are amended herein in order to expedite prosecution. The claims are modified by incorporating the limitations of the claims immediately after them, i.e., claims 40, 44, 50, and 52. Thus, claims 39 and 43 now include wherein the compounds comprise a "lignosulfonic acid (LSA)" and claims 49 and 51 now include wherein the lignin is a "sulfated lignin." Because of the incorporation of their limitations into the preceding claims, claims 40, 44, 50, and 52 are cancelled herein. Since the rejected claims no longer include the unmodified

language "at least one sulfonated compound" or "lignin," the rejection based on 35 U.S.C. §112 First Paragraph is moot and Applicants respectfully request that it be withdrawn.

In regard to the Office Action's allegation that the use of "spermicide" in claims 37, 43, and 51 is not enabled by the written description of the specification because only Nonoxynol 9™ is described, Applicants respectfully traverse.

The Office Action contends that spermicide "is seen to be merely functional language." The prior Office Action also alleged that such "functional language" is admonished by the court in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC, 1997), hereinafter Lilly. Both Office Actions quote from Lilly, and emphasize that satisfaction of the written description requirement "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." The Office Actions further allege since "spermicide" is a "purely functional distinction" and Nonoxynol 9™ is the only spermicide illustrated within the specification, that the written description for "spermicides" as a group is not satisfied. Applicants respectfully point out that other M.P.E.P. sections and case law are more pertinent than Lilly in the current analysis.

The M.P.E.P. analyzes Lilly in regard to written description requirements at, *inter alia*, §2163(II)(A)(3)(a)(ii). Notwithstanding the Office Actions' characterization of Lilly, however, the M.P.E.P. clearly states that situations exist "where one species adequately supports a genus." For examples of such situations, the M.P.E.P. cites to Rasmussen, 650 F.2d at 1214, 211 USPQ at 326-27; In re Herschler, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979); and In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973).

In re Herschler is particularly apt in the current context. The specification in Herschler disclosed corticosteroid in DMSO, while the claims were drawn to methods using a mixture of a "physiologically active steroid" and DMSO. The claims were found to be enabled in terms of written description. The court in Herschler stated that:

use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description **only so specific as to lead one having ordinary skill in the art to that class of compounds.** Herschler at 718 (emphasis added)

The situation in Herschler is easily analogous to the current application. As steroids were in Herschler, spermicides herein are known chemical compounds used in a manner auxiliary to the invention, and need only be described well enough to lead one of ordinary skill in the art to the class. The current specification contains sufficient written description for the class in question, by use of the term "spermicides" and the example of Nonoxynol 9™. See, e.g., paragraph 51.

Applicants submit that the term "spermicide," similar to the phrase "physiologically active steroid" in Herschler is well recognized by those of skill in the art. Those of skill would be aware of, and familiar with, various different spermicides and would easily understand, and not miscomprehend, the description in the specification. In other words, those of ordinary skill in the art would recognize the class of "spermicides." Spermicides are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend. See also Amgen v. Hoechst, 314 F.3d 1313 (Fed. Cir. 2003). Because of the above reasons Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §112 Second Paragraph.

Claims 35, 37, 49, and 51-52 were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite by failing to particularly point out and distinctly claim the subject matter regarded by applicants as the invention. More specifically, the Office Action alleges that the phrases "derivatives thereof" in claims 35 and 37 and "a derivative thereof" in claim 49 (and hence its dependents 51 and 52) render such claims indefinite. The Action states that one of ordinary skill in the art could not ascertain and interpret the metes and bounds as to "derivatives thereof" and "a derivative thereof" in the current application. Applicants herein amend the claims to remove such language.

Again, Applicants believe the unamended claims to be clear and not to be indefinite. However, in order to expedite prosecution, Applicants herein amend claims 35, 37, 49, and 51 to remove the phrases "a derivatve thereof" and "derivatives thereof." Claim 52 is cancelled herein, see *above*, and, thus, is not amended. Because the amended claims do not contain the language protested by the Office Action, Applicants respectfully request that the rejections be withdrawn.

35 U.S.C. §102(b).

Pillai

Claims 35, 39-42, and 49-50 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156). Applicants herein amend.

The Office Action alleges that Pillai discloses compositions having lignin-derived macromolecules "containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction."

While Applicants believe that Pillai does not disclose all elements of the unamended claims (e.g., because Pillai includes glutaraldehyde or paraformaldehyde which would render the composition to be unacceptable as a pharmaceutical excipient no matter the other constituents comprising the composition), Applicants herein amend claims 35, 39 (and hence its dependents 41-42), and 49, to recite "wherein the sperm is from a vertebrate, a mammal, a human, a canine, a feline, a rodent, an insect, a fish, an amphibian, or a reptile." Claims 40, and 50 were cancelled above. Support for such change is replete throughout the application as filed. *See, e.g.*, paragraphs 18, 40, and 45.

In order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. Applicants respectfully submit that Pillai does not teach every element of the amended claims. For example, Pillai does not teach compositions comprising a sperm from "a vertebrate, a mammal, a human, a canine, a feline, a rodent, an insect, a fish, an amphibian, or a reptile" as recited in amended claims 35 and 39.

Again, Pillai deals with sperm from sea urchins (an echinoidea), thus, Pillai does not include all the limitations of the amended claims and cannot anticipate the current claims. Because Pillai does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §103(a).

Pillai and Anderson

Claims 37, 43-44, and 51-52 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156) and Anderson et al. (USPN 6,063,773). Applicants respectfully traverse.

In brief, Applicants submit that the Office Action has not established a *prima facie* case of obviousness because the record fails to provide the elements necessary for a *prima facie* case.

M.P.E.P. §2144.06 quotes from In re Kerkhoven in setting forth the guidelines for establishing *prima facie* obviousness based on combining equivalents "known for the same purpose."

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, in order to have *prima facie* obviousness, the prior art compositions, as well as the resulting third composition, must have been useful for the same purpose. Kerkhoven based its rejections upon combination of two conventional spray-dried detergents. Kerkhoven at 1072. The court held that both components were detergents which were used for the very same purpose, i.e., they were dry, free-flowing detergents.

To try to establish *prima facie* obviousness, the Office Action alleges that [o]ne having ordinary skill in the art at the time the invention was made would have been motivated to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition since both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Office Action at page 12.

However, Applicants respectfully emphasize that the Office Action has mischaracterized the purposes of the elements (namely the lignosulfonate or lignosulfonic acid and the spermicide) in the current application. In other words, Applicants submit that the lignosulfonate or lignosulfonic acid and the spermicide are not "compositions known useful for the same purpose [...] form[ing] a third composition to be used for the very same purpose." The Office Action roughly lumps both LSA and spermicides together as "known to be useful in a composition for contraception or inhibiting fertilization."

Applicants respectfully point out, though, that such characterization is an incorrect analysis. Lignosulfonate/lignosulfonic acid (LSA), etc., is not a spermicide; rather, it, e.g., inhibits acrosome reaction of sperm. The specification emphasizes that the LSA herein does not act as a spermicide (i.e., does not kill sperm). See, e.g., paragraphs 42, 50 (which states that the "compounds. . . can allow the sperm to remain mobile while preventing or inhibiting fertilization of the oocyte by the treated sperm"), etc. In marked contrast, a spermicide kills sperm. Unlike LSA, the spermicide Nonoxonyl 9<sup>TM</sup> is actually cytotoxic to a number of cells in addition to sperm.

Thus, it can be seen that the two components are not useful for the very same purpose, which is required in order to create *prima facie* obviousness by combining equivalents.

The current components are as if in Kerkhoven (by analogy) one component had been a detergent, but the other component had been a bleaching agent or the like. Both may have been present together, but would have had different purposes. Similarly in the present application the LSA and the spermicide can be present together, but they still have quite different purposes.

The Office Action overly generalizes the uses/purposes of the compositions by setting the definition of "purpose" so far out from the actual intended uses/purposes of the compositions that the categorization is meaningless. Roughly defining the use/purpose of the compositions to be "contraception or inhibiting fertilization," is similar to defining HIV drug cocktails, which include different compositions (e.g., nucleoside analogs such as AZT and ddI and a protease inhibitor) as "obvious" because their use/purpose is to treat HIV patients. The end goal may be to treat the patient, but the actual uses/purposes of the compositions are vastly different. Similar analogies can be made to basically any combination drug treatment therapy.

Applicants submit that the Office Action generalizes the definition of use/purpose of the composition elements so much as to be meaningless. Since the LSA and the spermicide serve

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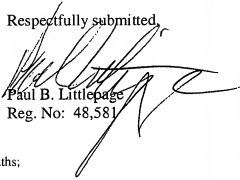
different purposes/uses, as noted above, *prima facie* obviousness cannot be established and Applicants respectfully request that the rejection be withdrawn.

### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. In the event that substantive matters are felt to remain, the Examiner is invited to telephone the undersigned at (510) 769-3507.

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Respectfully submitted,

  
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#### ATTACHMENTS:

- 1) A petition to extend the period of response for 3 months;
- 2) Notice of Appeal;
- 3) A Transmittal; and,
- 4) A Receipt Indication Postcard.